

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

TRANSLATION

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

		Date of mailing (day/month/year)
Applicant's or agent's file reference GP05-1005PCT		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/JP2005/006634	International filing date (day/month/year) 05.04.2005	Priority date (day/month/year) 16.04.2004
International Patent Classification (IPC) or both national classification and IPC		
Applicant OKABE, Hidetoshi		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT / JP2005/006634

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material

a sequence listing
 table(s) related to the sequence listing
 - b. format of material

in written format
 in computer readable form
 - c. time of filing/furnishing

contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.	PCT/JP2005/006634
-------------------------------	-------------------

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
-----------	--

1. Statement

Novelty (N)	Claims <u>1-12</u>	YES
	Claims _____	NO
Inventive step (IS)	Claims _____	YES
	Claims <u>1-12</u>	NO
Industrial applicability (IA)	Claims <u>1-12</u>	YES
	Claims _____	NO

2. Citations and explanations:

Document 1: Shari A. PRICE-SCHIAVI, RAT MUC4 REDUCES BINDING OF ANTI-ERBB2 ANTIBODIES TO TUMOR CELL SURFACES, A POTENTIAL MECHANISM FOR HERCEPTIN RESISTANCE, International Journal of Cancer, Vol. 99, 2002, p783-791, see Abstract

Claims 1-12

Document 1 describes that the HER2/c-erbB-2 antibody called herceptin is effective for breast cancer of high expression of HER2/c-erbB-2, and that the bonding of the said antibody to HER2/c-erbB-2 is hindered by Muc4. (see Abstract etc.)

If so, it could be easily practiced by a person skilled in the art to try a test of the effectiveness of a herceptin therapy as to how much interfering Muc4 exists will influence the effectiveness in order to check whether or not the said herceptin can be bonded to its target HER2/c-erbB-2, in addition to checking whether or not HER2/c-erbB-2 has high expression.

Therefore, claims 1-12 do not appear to involve an inventive step.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2005/006634

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

- (1) Claims 11 and 12 are the inventions related to a reagent and reagent kit. But the descriptions of claim 11 and 12 refer to an examination method. So, the structure of reagent and reagent kit is not clear.